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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,302	01/30/2002	Randall T. Lashinski	MITRAL.001CP2	2373
20995	7590	06/29/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			CHATTOPADHYAY, URMI	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3738	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/066,302

Applicant(s)

LASHINSKI ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-32, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 9, 10, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 11-14, 17-32, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

DR

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 4/1/04 has been entered. The changes to the specification and Figures 5, 15E and 20 have been approved by the examiner. Claims 4 and 33-37 have been canceled. Claims 1-3, 5-32, 38 and 39 are pending, of which claims 5-7, 9, 10, 15 and 16 remain withdrawn from consideration. Claims 1-3, 8, 11-14, 17-32, 38 and 39 are being considered for further examination on the merits.

### ***Allowable Subject Matter***

2. The indicated allowability of claims 4, 8, 20-32, 38 and 39 is withdrawn in view of the newly discovered reference(s) to Webster, Jr. (USPN 6,123,699), Vidlund et al. (USPAP 2003/0130731), Alferness et al. (USPAP 2002/0169504) and reconsideration of Wilson et al. (USPN 5,304,131), which has already been cited. Rejections based on the newly cited reference(s) follow. This office action is non-final.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-3, 8, 12-14, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,569,198 as cited in applicant's IDS) in view of Paskar (USPN 5,304,131).

Wilson et al. discloses a mitral valve annuloplasty prosthetic device with all the elements of claim 1, but is silent to the tubular body having a plurality of transverse slots therein to permit flexing in at least one plane. See Figure 2 for an elongate tubular body (12) and a forming element (48) attached to the elongate body for manipulating the body from the first transluminal configuration to the second remodeling configuration. Threaded aperture (96) of a nub (94) provides as a lock with threaded section (98) of forming element (48), wherein the lock is capable of retaining the body (12) in the second configuration. Paskar teaches forming a plurality of transverse slots (75, 77, 79) in a tubular body in order to form a predetermined region of weakness. As a result, tension being applied to a wire attached to the distal end of the tubular body bends in the direction of the predetermined weakness. See column 7, lines 51-64. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Paskar to modify the device of Wilson et al. by including a plurality of slots in the tubular body. The slots will provide the body with a predetermined region of weakness so that when the device is deployed from the catheter, the body will bend only in the direction of the predetermined weakness, towards the mitral valve annulus. This will aid in the proper orientation of the device within the coronary sinus.

Claim 2, see Figure 5 for the elongate body forming an arc when in the remodeling configuration, which may be done by changing the shape of the slots.

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With respect to claims 3, 18 and 19, because of the radius of curvature and dimensions of the coronary sinus, it is inherent that the best fit constant radius curve, axial length and cross-sectional dimension of the apparatus will not exceed the values required by these claims.

With respect to claim 8, the lock is disengaged and engaged when the threaded aperture (96) and threaded section (98) of the forming element (48) are disengaged and engaged, respectively.

Claims 12 and 13, see column 6, lines 31-33 and column 7, lines 55-57 for proximal retraction or distal advancement.

Claim 14, see Figures 4a-4b for anchor (72).

5. Claims 11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. in view of Paskar as applied to claim 1 above, and further in view of Solem et al. (USPN 6,210,432).

Wilson et al. and Paskar disclose a mitral valve annuloplasty prosthetic device with all the elements of claim 1, but is silent to the additional limitation of a coating on the body, as required by claim 11. Solem et al. teaches a mitral valve annuloplasty device wherein a coating of heparin is applied to the device in order to avoid thrombosis in the coronary sinus, and thus reduce the need for aspirin, ticlopedine or anticoagulant therapy. See column 5, lines 14-17. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Solem et al. to modify the device of Wilson et al. and Paskar by including a coating, specifically of heparin, to the body in order to avoid thrombosis in the coronary sinus, and thus reduce the need for aspirin, ticlopedine or anticoagulant therapy.

Wilson et al. and Paskar are also silent to the additional limitation of the anchor comprising at least one barb for piercing the wall of the vessel, as required by claim 17. Solem et al. teaches an anchor comprising at least one barb for piercing the wall of the vessel in order to retain the device within the vessel at the desired location. See column 4, lines 23-25. While the spring coil mechanism of Wilson et al. and the barbs of Solem et al. serve the same purpose of anchoring, the barbs are much more simple than the coil mechanism. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention, therefore, to look to the teachings of Solem et al. and replace the coil mechanism of Wilson et al. with the barbs of Solem et al. in order to reduce the complexity of the device.

6. Claims 20-28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. (USPAP 2003/0130731) in view of Alferness et al. (USPAP 2002/0169504).

Vidlund et al. discloses an implant for positioning within a patient in the coronary sinus for treating the mitral valve with all the elements of claim 20, but is silent to a detachable coupling on a proximal portion of the body. See Figures 4h-4i and [0124] for an elongate flexible body (110h) having proximal and distal ends and a longitudinal axis extending therebetween. A first side has a fixed axial length and opposing second side has an adjustable axial length. A first forming element (90) extends through the body to a distal point of attachment and deflects a first portion of the body away from the longitudinal axis, as shown in Figure 4i. See [0125] for the implant being implanted using a catheter. Alferness et al. teaches a mitral valve therapy device (30) that has a detachable coupling (46) on the proximal portion (44) of the device in order to removably attach with an introducer (56) that is used for positioning the

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device (30) in the coronary sinus. See [0050], [0054] and Figures 2 and 3. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings Alferness et al. to modify the implant of Vidlund et al. by including a detachable coupling on a proximal portion of the body in order to removably attach with an introducer in the form of a catheter. The forming element (90) will extend through a lumen of the catheter and the catheter will be used to position the implant in the coronary sinus.

Claim 21, see Figure 4i for the body comprising a tubular wall.

Claim 22, see Figure 4h for a substantially non-compressible first side.

Claims 23 and 24, see Figure 4h for a plurality of voids along the second side in the form of slots extending transverse to the longitudinal axis and permitting axial shortening on the second side.

Claims 25 and 26, see Figure 4h for required number of slots.

Claims 27 and 28, see [0124] for the first forming element being an axially movable pull wire.

Claims 31 and 32, see [0124] and Figures 4h-4i for axial elongation and axial compression of the second side with distal and proximal movement, respectively, of the forming element (90), thereby bending the implant.

7. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. and Alferness et al. as applied to claim 20 above, and further in view of Webster, Jr. (USPN 6,123,699).

Vidlund et al., as modified by Alferness et al., discloses an implant for positioning within a patient with all the elements of claim 20, but is silent to the additional limitation of at least a second forming element, as required by claim 29. See [0124] of Vidlund et al. for the elongated body (110h) having a final shape with an increased radius of curvature in some regions and a decreased radius of curvature in other regions. Webster, Jr. teaches a steerable catheter wherein four puller wires (31) are anchored at three or four different locations along the length of the distal tip of the catheter in order to provide each quadrant with a distinct curvature. See column 7, lines 47-52. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Webster, Jr. to modify the implant of Vidlund et al. and Alferness et al. by including at least a second forming element attached at a different location than the first forming element (90) along the length of the implant body (110h) in order for the first forming element (90) to introduce a first curve in the body and the second forming element to introduce a second curve in the body (claim 30). This will provide more control in achieving an implant with specific regions of increased and decrease radii of curvature.

8. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. in view of Paskar.

Webster, Jr. discloses a steerable catheter that can provide as a vascular implant with all the elements of claim 38, but is silent to a plurality of transverse voids on the tubular body. See Figure 7 for the vascular catheter implant comprising a tubular body (13), and column 7, lines 47-52 for four puller wires (31) being anchored at three or four different locations along the length of the tubular body (13) in order to provide each quadrant with a distinct curvature. The

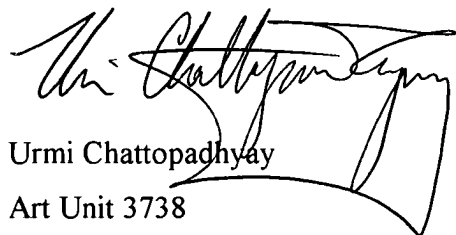


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pull wires (31) provide as first, second and third (claim 39) control wires for imparting curvature in first, proximal zone, second, distal zone, and third zone. Paskar teaches forming a plurality of transverse slots (75, 77, 79) in a tubular body in order to form a predetermined region of weakness. As a result, tension being applied to a wire attached to the distal end of the tubular body bends in the direction of the predetermined weakness. See column 7, lines 51-64. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Paskar to modify the vascular catheter implant of Webster, Jr. by including a plurality of slots in each of the zones of the tubular body (13). The slots will provide the body with predetermined regions of weakness so that the body will bend only in the direction of the predetermined weakness in that zone with proximal drawing of the respective control wire. This will aid in configuring the vascular catheter implant for the vessel in which it is implanted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



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Art Unit 3738



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